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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,934	07/24/2003	Kenneth David Reginald Setchell	CHM-013M1	9470

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 10/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/625,934

Applicant(s)

SETCHELL ET AL.

Examiner

Susannah Chung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-19 and 27-49 is/are pending in the application.
- 4a) Of the above claim(s) 6-11,27-43 and 46-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 3, 12-19, and 44-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/14/03; 3/15/04, 3/31/04, 4/13/04, 9/17/04, 11/1/04; 10/14/05, 11/21/05; 10/4/06.

DETAILED ACTION

Claims 1-2, 4-19, 27-48 and 49 are pending in the instant application. Claims 3, 20-25 and 26 are canceled. Claims 6-11, 27-43, 46-48 and 49 are withdrawn from consideration.

Priority

This application claims benefit of U.S. Provisional App. No. 60/398,270, filed 07/24/2002.

Information Disclosure Statement

The information disclosure statement (IDS), filed on 11/14/03, 3/15/04, 3/31/04, 4/13/04, 9/17/04, 11/1/04, 10/14/05, 11/21/05, and 10/4/06 have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Election/Restrictions

Applicant's election *without traverse* of Group I in the reply filed on 09/14/2006 is acknowledged. New claims 46-49 are acknowledged. New claims 46-49 are directed to "A food supplement" and is not within the scope of the elected invention, i.e. "A composition" or "A food composition," and therefore will not be examined at this point in time.

Scope of the Elected Invention

Claims 1, 2, 4-19, 27-48, and 49 are pending in this application.

The scope of the elected subject matter that will be examined and searched is as follows: Claims 1, 2, 4, 5, 12-19, 44 and 45, directed to a composition for use in making commercial products, consisting essentially of the S enantiomer of equol (S-equol), 7-hydroxy-3-(4'-hydroxyphenyl)-chroman.

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Scope of Withdrawn Subject Matter

Claims 6-11, 27-43, and 46-49 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2, 4-5, 12-17, 19, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorbach et al., U.S. Pat. No. 6,060,070 ('070 Patent).

Applicant's instant elected invention teaches a composition for use in making commercial products and food compositions, consisting essentially of the S enantiomer of equol (S-equol).

Determination of the scope and content of the prior art (MPEP § 2141.01)

Gorbach discloses compositions containing equol for use in making commercial products and food compositions, which reads on the instant claims. Gorbach claim 1 discloses a method of treating aging using equol. Claim 2 discloses that the dosage is at least 20 mg per serving. Claims 6 through 9 disclose the use of equol in commercial products and food compositions such as a confectionary bar, cereal, biscuit, beverage, or medicament.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art of Gorbach and the instant claims is that in the prior art the racemic mixture is disclosed, while the s enantiomer is in the instant application.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

However, in the absence of showing unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with Gorbach to make useful commercial products and food compositions, selecting one of the isoflavonoids Gorbach disclosed. A stereoisomer is not patentable over its known racemic mixture unless it possesses unexpected properties not possessed by the racemic mixture. In re Anthony, 162 USPQ 594, 596 (1969) and In re Adamson, 125 USPQ 233, 234 (1960).

MPEP 2112 states the express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 USC 102 or 103. Something which is old does not become patentable upon the discovery of a new property. See In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorbach et al., U.S. Pat. No. 6,060,070 ('070 Patent) in view of Miller et al., U.S. Pat. No. 6,159,959 ('959 Patent).

Applicant's instant elected invention teaches a composition for use in making commercial products and food compositions, consisting essentially of the S enantiomer of equol (S-equol).

Determination of the scope and content of the prior art (MPEP § 2141.01)

Gorbach discloses compositions containing equol for use in making commercial products and food compositions, which reads on the instant claims. Gorbach claim 1 discloses a method of treating aging using equol. Claim 2 discloses that the dosage is at least 20 mg per serving.

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Claims 6 through 9 disclose the use of equol in commercial products and food compositions such as a confectionary bar, cereal, biscuit, beverage, or medicament.

Miller discloses compositions containing equol for use in making commercial products and food compositions, which reads on the instant claims. Miller claim 18 discloses a composition, wherein equol is combined with one or more glucuronide, sulfate, acetate, propionate, glucoside, acetyl-glucoside, malonyl-glucoside and mixtures thereof.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the prior art of Gorbach and Miller and the instant claims is that the instant claims are broader (i.e. forming a conjugate with equol, selected from the group consisting of glucuronide, sulfate, etc...), while in the prior art the claim is more specific (i.e. forming a composition combining equol and 20-R-tiol-3-sodium sulfate (see second to last line of claim 18)).

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

However, in the absence of showing unobvious results, it would have been obvious to one of ordinary skill in the art at the time of the invention when faced with Gorbach and Miller to make commercially useful products and food compositions, selecting equol and one of the specific sulfates Miller disclosed. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...the idea of combining them flows logically from their having been individually taught in the prior art. MPEP 2144.06. The instant claims state that S-equol is conjugated at the C-4' or C-7 position to form a conjugate selected from the group consisting of glucuronide, sulfate, etc... or mixtures thereof. The prior art discloses

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mixtures using equol and specific glucuronide, sulfate, etc... groups. Also, it is well known in the art that equol is usually substituted at the C-4' and C-7 positions because that is where the hydroxyl groups are in the compound.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 19 are improperly dependent from Claim 16 for failure to limit the scope of Claims 16. Claims 17 and 19 are drawn to a composition for topical application to skin, comprising ..., which recites the intended use of the compounds. However, intended use is not a limitation of a compound. *In re Hack*, 114 PQ 161 (CCPA 1957). Therefore, Claims 17 and 19 are improper. By deleting Claims 17 and 19, the rejection would be overcome.

Claim Objections

Claims 2 and 16 are objected to under 37 CFR 1.75 as being a substantial duplicate of claim 1. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Stereochemistry is an inherent property of a compound and is not a further limitation of the compound.

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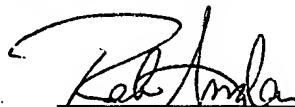
Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Chung
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for Joseph K. McKane
Supervisory Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

Date: 10 October 2006